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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,083	10/20/2003	John Allen	LFS-5002	4870

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EXAMINER
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SONNETT, KATHLEEN C

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 04/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/690,083

Applicant(s)

ALLEN ET AL.

Examiner

Kathleen Sonnett

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☒ Claim(s) 1, 7 and 10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10/20/03, 1/24/05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: IDS on 3/1/05.

## **DETAILED ACTION**

### ***Claim Objections***

**Claims 1, 7, and 10** are objected to because of the following informalities:

typographical errors on line 9 of claim 1, line 3 of claim 7, and the last line of claim 10.

The "t" has been omitted from "lancet carriage" in claims 1 and 10. Line 3 of claim 7 reads, "wherein the floating probe spring, launcher spring, and floating probe spring are...". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 1, 2, 4, 6- 8, 10, and 11** are rejected under 35 U.S.C. 102(b) as being anticipated by Douglas et al. (U.S. 5,857,983). Douglas et al. discloses a lancing device comprising a lancet carriage (74), a lancet holder (42) slidably connected to the lancet carriage, a lancet (26) attached to the lancet holder and a floating probe (70). Douglas et al. further discloses a pressure tip (72) for engaging a target site and creating a target site bulge. The floating probe is adapted to floatably contact the target site bulge and is

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configured to operatively interact with the lancet carriage to control the penetration depth of the lancet into the bulge. The floating probe is connected to the lancing carriage and the position of the carriage within vertical slots (78) determines the penetration depth of the lancet as it can only move toward the target site until the bottom of tube (30) engages recess (98) as seen in Fig. 8 and 9.

Regarding **claim 2**, the lancet carriage and the floating probe are slidably connected to the housing (12) through pins (76) and slots (78).

Regarding **claim 4**, Douglas et al. discloses a launcher spring (58) and a decoupling spring (56) arranged in series.

Regarding **claim 6**, the device further comprises a stop lock assembly (34,36,38 col. 6 lines 21-25).

Regarding **claim 7**, the device includes a launcher spring (58) and a floating probe spring (60). Spring element (56) is now being considered the over-travel spring. These springs act to control movement and positioning of the floating probe, lancet carriage, and lancet holder. Movement and positioning of the floating probe and lancet carriage relative to the other units are controlled by the springs since these springs move the remaining elements of the lancing device with respect to the floating probe and lancet carriage.

Regarding **claim 8**, the pressure tip has a surface (bottom of slots 78) that limits longitudinal movement of the lancet carriage. The lancet carriage is attached to the floating probe surface and therefore, longitudinal movement of the probe is stopped as well.

Regarding **claim 10**, Douglas et al. discloses the structure of the lancing device as stated above. Douglas et al. also discloses the method of lancing a target site, the method comprising contacting the pressure tip with the target site (col. 6 lines 30-32). When the pressure tip is applied at the target site, a bulge will be created and the floating probe will site on the surface of the bulge as shown in Fig. 1 and 2. As stated above, the lancet carriage and floating probe operatively interact to control the penetration of the lancet as well as the depth of the penetration.

Regarding **claim 11**, elements (80, 86, 88) are now being considered the stop lock assembly. When the lancing step lances the target site bulge, this stop lock assembly prevents movement of the floating probe until element 88 is actuated to move the lancet carriage and floating probe vertically within slots (78) (col. 6 lines 3-15 and lines 44-46).

**Claims 1-3, 6, 8, 9, and 10-11** are rejected under 35 U.S.C. 102(e) as being anticipated by Roe et al. (U.S. 2004/0127818). Roe et al. discloses a lancing device comprising a lancet carriage (66), a lancet holder (50) slidably connected to the lancet carriage, a lancet (58) attached to the lancet holder, a floating probe (82) and a pressure tip (92). The floating probe is adapted to floatably contact the target site bulge and is configured to operatively interact with the lancet carriage to control penetration depth of the lancet into the bulge ([0070]). The lancet carriage and the floating probe are slidably connected to the housing and the lancing holder is slidably connected to the lancet carriage (see Fig. 4 and 5). The lancet is made of metal while the remaining elements of the lancing device are made of plastic, which is a rigid material ([0075]).

Regarding **claim 6**, the lancing device comprises a stop lock assembly (44, 60, [0070]).

Regarding **claim 8**, the pressure tip includes a probe stop surface (90) (see Fig. 1 and 5, [0066])

Regarding **claim 9**, the lancet carriage includes a lancet holder over-travel stop feature (74).

Regarding **claims 10-11**, Roe et al. discloses the structure of the invention in claim 10 as stated above, and also discloses the method for lancing a target site. As seen in Fig. 3, the pressure tip contacts the target site, the pressure tip is urged toward the target site creating a bulge, and the target tissue is lanced while the floating probe operatively interacts with the lancet carriage to control a penetration of the lancet. The stop lock assembly (44, 60) locks the lancet carriage and floating probe in place so that the tissue is lanced with a predetermined penetration depth ([0068], [0070]).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claim 3** is rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas et al. in view of Shrager (U.S. 6,022,366). Douglas et al. discloses the invention

substantially as stated above, but fails to disclose what the floating probe is formed from.

However, Shraga discloses that it is old and well known in the art to use rigid materials for lancet devices. The rigid plastic material disclosed by Shraga is lightweight and strong so that it can be reused. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device disclosed by Douglas et al. to include a floating probe formed from a rigid material made obvious by Shraga in order to provide a lancing device that is strong and can be reused.

**Claim 4** is rejected under 35 U.S.C. 103(a) as being unpatentable over Roe et al. in view of Douglas et al. Roe et al. discloses the invention substantially as stated above, including a decoupling spring (94). Roe et al. fails to disclose a launcher spring that is in series with the decoupling spring.

However, Douglas et al. discloses that it is old and well known in the art to include a spring system in series in a lancet system. The spring system disclosed by Douglas et al. controls the movement of the lancet holder with respect to the housing and trigger mechanism. A second spring in series with the decoupling spring (94) of Roe et al. could be added to control the movement of lancet holder (42) as it is not disclosed exactly how the position of the lancet holder is maintained when not depressed by the user. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device disclosed by Roe et al. to include a launcher spring made obvious by Douglas et al. in order to provide a control for the positioning of the lancet holder relative to the lancet carriage.

**Claim 5** is rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas et al. in view of Böcker et al. (U.S. 5,997,561). Douglas et al. discloses the invention substantially as stated above, but fails to disclose that the penetration depth is between 0.25mm and 1.5 mm.

However, Böcker et al. discloses that it is old and well known in the art to include a penetration depth of 0.25 mm to 1.5 mm in a lancing device that has a depth of penetration controlling means. Böcker et al. discloses that the penetration depth range can be set between 0.2 and 2.0 mm in order to provide about 100 microliters of body fluid. A penetration depth of more than 2.0 mm can cause unnecessary pain. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device disclosed by Douglas et al. to include a penetration depth of between 0.25 mm and 1.5 mm made obvious by Böcker et al. in order to collect an appropriate amount of fluid for blood sampling while minimizing pain felt by the user.

**Claim 5** is similarly rejected under 35 U.S.C. 103(a) as being unpatentable over Roe et al. in view of Böcker et al. (U.S. 5,997,561). Roe et al. discloses the invention substantially as stated above, but fails to disclose that the penetration depth is between 0.25mm and 1.5 mm. However, Böcker et al. discloses that it is old and well known in the art to include a penetration depth of 0.25 mm to 1.5 mm in a lancing device that has a depth of penetration controlling means. Böcker et al. discloses that the penetration depth range can be set between 0.2 and 2.0 mm in order to provide about 100 microliters of body fluid. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device disclosed by Roe et al. to include a penetration depth of



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between 0.25 mm and 1.5 mm made obvious by Böcker et al. in order to collect an appropriate amount of fluid for blood sampling.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KCS  
April 12, 2006

  
**ANH TUAN T. NGUYEN**  
**SUPERVISORY PATENT EXAMINER**

4/15/06.